

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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89/249,220 02/12/99 MUELLER

R BRL-6109

000321 HM12/1122  
SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS MO 63102

EXAMINER

GHASHGHAIEE, F

ART UNIT	PAPER NUMBER
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1656

6

DATE MAILED:

11/22/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/249,220	MUELLER ET AL.
	Examiner	Art Unit
	Fariba Ghashghaee	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1) Responsive to communication(s) filed on 14 August 2000.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-149 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-149 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:

1. received.

2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.

3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 + 4

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 92 recites the limitation of a method in claim 85, which is a composition claim, there is insufficient antecedent basis for this limitation in the claim.

Claims 1-46,49-55, 59-115, and 118-124 are drawn to composition and the method of use of the composition for treatment of anti-viral and anti-HBV by 1,5-dideoxy-1,5-imino-D-glucitol and its N-(substituted) derivatives.

Claims 47, 56, 116, and 125 are drawn to the composition and the method of use of the composition for the treatment of antiviral and anti-HBV by 2,3-dideoxy-3-thiacytidine-triphosphate and its derivatives.

Claims 48, 57, 58, 117, 126, 127, 135, 136, 148, and 149 are drawn to the method of use of the mixtures of the 1,5-dideoxy-1,5-imino-D-glucitols and thiocytidine complexes for treatment of the antiviral and anti-HBV and administration of this mixture to the patients.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-46, 49-55, 59-115, and 118-124 are rejected under 35 U.S.C. 102(b) as being anticipated by Partis, et al. (US Patent 5,147,037 issued on Sep. 1, 1992).

Partis, et al. discloses the preparation of 1,5-dideoxy-1,5-imino-D-glucitol and a large number of its N-(substituted) glucitols that contain N-alkyl, N-aroyl, N-acyl, and N-alkanoyl derivatives. Within the N-alkyl groups, butyl, pentyl, hexyl, nonyl are shown in the examples. n-nonyl (column 11, example 13), butyl and their tetrabutyrate salts (column 12, example 16 and column 24, example 44). Partis, et al. also discloses that these antiviral agents can be used for administration to a mammalian host infected with a lentivirus, e.g. Visna virus or the human immunodeficiency virus, by conventional means, preferably in formulations with pharmaceutically acceptable diluents and carriers.

Claims 47, 56, 116, 125, and 134 are rejected under 35 U.S.C. 102(b) as being anticipated by Schinazi, et al. (US Patent 5,703,058 issued on Dec. 30, 1997)

Schinazi, et al. discloses the preparation of 2,3-dideoxy-3'-thiocytidine and many of its derivatives and their significant antiviral and anti-HBV activity and administration of these compounds to human patient (columns 13 and 14, examples 4 and 5).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48, 57, 58, 117, 127, 135-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partis, et al. in view of Schinazi, et al.

Partis, et al. discloses the preparation of 1,5-dideoxy-1,5-imino-D-glucitol and a large number of its N-(substituted) derivatives as discussed earlier. Partis, et al. also discloses that these N-(substituted)-glucitol compounds are very effective antiviral and anti-HBV agents.

The claims differ from Partis, et al. in the recitation of the preparation or the use of 2,3-dideoxy-3'-thiacytidine and its derivatives and their significant antiviral and anti-HBV activity and administering to human patients.

However, Schinazi, et al. discloses the preparation of 2,3-dideoxy-3'-thiocytidine and a large number of its derivatives and also discloses their effective antiviral and anti-HIV activity and administering these drugs to human patients as discussed earlier (columns 13 and 14, examples 4 and 5).

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Furthermore, Schinazi, et al. discloses the synergistic effect of mixing these thiacytidine compounds with other antiviral, anti-HIV, and anti-HBV agents for treating the effected human patients (in column 20, lines 6-12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare the N-(substituted)-1,5-dideoxy-1,5-imino-D-glucitol compounds by using Partis, et al. reference and 2,3-dideoxy-3'-thiocytidine compounds by Schinazi, et al. reference and combine these two antiviral compositions to treat patients affected by these viral infections.

One of the ordinary skill in the art would have been motivated to prepare these two groups of antiviral compounds and combine them to make more effective antiviral drug and determine the useful dosage by experience, and reasonably would have expected success because Schinazi, et al. (column 20, lines 6-12) discloses that 2,3-dideoxy-3'-thiocytidine compounds could also be mixed with other antivirals and anti-HIV compounds to increase their effectiveness.

#### PRIOR ART

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are Partis, et al.(US Patent 5,003,072), Bryant, et al.(US Patent 5,622,972), Partis, et al.(US Patent 5,221,746), Fleet , et al.(US Patent 4,849,430), and Malley, et al.(US Patent 6,093,702).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fariba Ghashghae whose telephone number is (703)305-3586. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703)308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3014 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



F.G. Ghashghae  
November 17, 2000



SCOTT W. HOUTTEMAN  
PRIMARY EXAMINER